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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,524	09/20/2005	Caroline Hoemann	701826-056360	2128
<div>7590 David S Resnick Nixon Peabody 100 Summer Street Boston, MA 02110-2131</div>			<div>EXAMINER BARNHART, LORA ELIZABETH</div>	
			<div>ART UNIT 1651</div>	<div>PAPER NUMBER</div>
			<div>MAIL DATE 07/24/2008</div>	<div>DELIVERY MODE PAPER</div>

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/521,524	Applicant(s) HOEMANN ET AL.	
	Examiner Lora E. Barnhart	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 and 41-44 is/are pending in the application.
- 4a) Of the above claim(s) 20-29 and 41-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19, 30 and 44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant should note that the examiner for this case has changed.

Response to Amendments

Applicant's amendments filed 3/27/08 to claims 1-5, 7, 16, and 18 have been entered. Claims 31-40 have been cancelled. No claims have been added. Claims 1-30 and 41-44 remain pending in the current application, of which claims 1-19, 30, and 44 are being considered on their merits. Claims 20-29 and 41-43 remain withdrawn from consideration at this time.

Claim Rejections - 35 USC § 112

Any rejections of record under 35 U.S.C. § 112 not particularly discussed below are withdrawn in light of the claim amendments.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-19, 30, and 44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 1 as amended is drawn to a composition comprising a liquid polysaccharide solution of isotonic neutral chitosan and "a cross-linking solution consisting of glyoxal." However, the specification clearly indicates that the cross-linking

Art Unit: 1651

solution contains at least two components: a polymer and a physiological media (see, e.g., paragraphs 9-13 and 55 of the as-filed specification). The transitional phrase "consisting of" excludes any element, step, or ingredient not specified in the claim. *In re Gray*, 53 F.2d 520, 11 USPQ 255 (CCPA 1931); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948). See M.P.E.P. §2111.03. The specification includes no guidance for making a composition that would be suitable for immobilizing and encapsulating viable cells or bioactive substances in which the cross-linking solution contains glyoxal and only glyoxal (see, e.g., paragraph 55, in which glyoxal is mixed with physiological medium). It appears from the specification that the cross-linking solution necessarily contains at least one component other than glyoxal, i.e. a diluent, as an essential feature. The claims should reflect this critical component.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 3, 30, and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 requires that the cross-linking solution of claim 1 comprise two components that are not recited in claim 1. A claim which depends from a claim which "consists of" the recited elements or steps cannot add an element or step. When the phrase "consists of" appears in a clause of the body of a claim, rather than immediately following the preamble, it limits only the element set forth in that clause; other elements are not excluded from the claim as a whole. *Mannesmann Demag Corp. v. Engineered*

Art Unit: 1651

Metal Products Co., 793 F.2d 1279, 230 USPQ 45 (Fed. Cir. 1986). See M.P.E.P. § 2111.03. In other words, claims that depend from claim 1 cannot add elements to the cross-linking solution of claim 1, since this solution consists of a single element. Clarification is required.

Furthermore, it is not clear whether the glyoxal of claim 1 is the cross-linker recited in claim 2 or whether claim 2 is intended to allow that there is an additional cross-linker. Clarification is required.

Claim 3, like claim 2, adds elements to the cross-linking solution of claim 1, which is improper. Claim 44 depends from claim 3 and is indefinite for the same reasons. See M.P.E.P. § 2111.03. Clarification is required.

Claim 30 depends from claim 1 and recites the limitation “[the] hydroxyl-containing polymer.” There is no antecedent basis for this limitation in claim 1. Clarification is required.

Claim Rejections - 35 USC § 102

The rejection of record under 35 U.S.C. § 102 is withdrawn in light of the claim amendments and the submission of affidavits under 37 C.F.R. 1.131. The following new grounds of rejection are necessitated by applicant’s amendments to the claims, which change the necessary components in the claimed composition.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 7, 13, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Scopelianos (1989, U.S. Patent 4,877,775; reference A). The claims are interpreted as being drawn to a composition comprising a solution of chitosan and a cross-linking solution consisting of glyoxal. This rejection reads on the embodiment in which the polysaccharide in element (a) of claim 1 is chitosan itself.

Scopelianos teaches a composition comprising an acidic solution of chitosan and a solution of glyoxal; when the glyoxal solution is combined with the chitosan solution, a gel forms immediately (Example 3 at column 5, lines 26-62). Scopelianos further teaches including bile acids in the composition (see Table 3 at column 6).

Applicant's comments regarding the withdrawn art rejection of record have been considered, but they do not address the above rejection.

Claim Rejections - 35 USC § 103

The following new grounds of rejection are necessitated by applicant's amendments to the claims, which change the necessary components in the claimed composition.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

Art Unit: 1651

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, 4, 6-8, 12-14, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dumitriu et al. (1997, U.S. Patent 5,620,706; reference B) taken in view of Scopelianos (1989, U.S. Patent 4,877,775) and Chen (1998, U.S. Patent 5,830,503; reference C). The claims are interpreted as being drawn to a composition comprising a solution of chitosan and a cross-linking solution consisting of glyoxal. In some dependent claims, the composition contains an additional polysaccharide that is hydroxyethyl cellulose (HEC) and contains particular amounts of chitosan and HEC. In some dependent claims, the composition comprises phosphate buffer and salt. This rejection reads on the embodiment in which the polysaccharide in element (a) of claim 1 is one other than chitosan. In the interest of compact prosecution, indefinite claims 2 and 3 have been interpreted as though claim 1 required the cross-linking solution to comprise glyoxal.

Dumutriu teaches a hydrogel for encapsulation of bioactive substances made by mixing an acidic chitosan solution with a solution of xanthan (Example 1; column 3, lines 49-67). Dumutriu teaches that the hydrogel may contain active agents such as enzymes and is compatible with physiological buffers (column 6, lines 24-38).

Dumutriu does not teach a composition containing glyoxal. Dumutriu does not teach a composition in which the polysaccharide is HEC.

Scopelianos teaches that glyoxal, when added to solutions of chitosan, promotes gelling of the chitosan (Examples 3a-3c at column 5).

Chen teaches that both xanthan and HEC are hydrogel-forming polymers acceptable in encapsulating bioactive substances (column 2, lines 27-53).

A person of ordinary skill in the art would have had a reasonable expectation of success in adding the glyoxal solution of Scopelianos to the chitosan/xanthan solution of Dumutriu because Scopelianos teaches that glyoxal causes chitosan to form a gel. The skilled artisan would have been motivated to include glyoxal in the composition of Dumutriu in order to make a gel immediately.

A person of ordinary skill in the art would have had a reasonable expectation of success in substituting HEC for xanthan in the composition of Dumutriu because xanthan and HEC are hydrogel-forming polymers that can be used to encapsulate bioactive substances. Therefore, these compositions are functional equivalents in the art, and substituting one for the other would have been obvious at the time of the invention. "When a patent 'simply arranges old elements with each performing the same function it had been known to perform' and yields no more than one would expect from such an arrangement, the combination is obvious." See *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007) at 1395-1396, quoting *Sakraida v. AG Pro, Inc.*, 425 U.S. 273 (1976).

The selection of the component in which to include HEC (i.e., the chitosan solution or the glyoxal solution) would have been a routine matter of optimization on the part of the artisan of ordinary skill, since the cited prior art suggests that when chitosan, HEC, and glyoxal are combined, a hydrogel suitable for immobilizing bioactive substances is yielded; the order in which the components are added is not inventive in the absence of evidence to the contrary. In *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946), the court found that selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results. In *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930), the court found that selection of any order of mixing ingredients is *prima facie* obvious. See M.P.E.P. § 2144.

The selection of the amount of each component to include in the composition would have been a routine matter of optimization on the part of the artisan of ordinary skill, said artisan recognizing that Dumutriu teaches that different amounts of chitosan and polysaccharide may be included (see the Examples and column 13, e.g.). A holding of obviousness over the cited claims is therefore clearly required.

A person of ordinary skill in the art would have had a reasonable expectation of success in including physiological diluents such as phosphate buffer, salt solutions, and other nutrients in the composition of Dumutriu because Dumutriu teaches that the composition is compatible with additional components (column 6, lines 35-38). The skilled artisan would have been motivated to include such diluents because Dumutriu teaches that the composition is intended for administration to subjects.

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was made to substitute HEC for xanthan and to add glyoxal to the composition of Dumutriu because Scopelianos teaches that glyoxal promotes rapid gel formation of chitosan compositions and Chen teaches that xanthan and HEC are equivalent polysaccharides in the bioactive substance encapsulation art. It would have been further obvious to include HEC in the glyoxal solution of Scopelianos or to include physiological buffers in the chitosan solution of Dumutriu for the reasons set forth above.

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

Applicant's comments regarding the withdrawn art rejection of record have been considered, but they do not address the above rejection.

Claims 2, 5, 9-11, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dumutriu, Scopelianos, and Chen as applied to claims 1, 3, 4, 6-8, 12-13, and 44 above, and further in view of Gombotz et al. (1999, U.S. Patent 5,900,238; reference D). The claims are interpreted as above. In some dependent claims, the composition further comprises a hydroxylated polymer, for example polyvinyl alcohol or dextran. In some dependent claims, the chitosan solution contains dilute acid and a polyol salt, for example glycerol-2-phosphate.

The teachings of Dumutriu, Scopelianos, and Chen are relied upon as above. None of Dumutriu, Scopelianos, and Chen teaches a composition comprising cells.

Gombotz teaches that compositions useful for encapsulating bioactive substances may include components that promote adhesion of the composition to tissues, e.g. polyvinyl alcohol, dextrans, and pluronic polyols (column 6, line 55, through column 7, line 4).

The selection of bioadhesive components to include in a hydrogel made by combining chitosan, a polysaccharide such as HEC, and glyoxal as suggested by Dumutriu, Scopelianos, and Chen would have been a routine matter of optimization on the part of the artisan of ordinary skill, said artisan recognizing that Gombotz teaches that hydroxyl-containing polymers and ionic polyols are useful in such compositions. A holding of obviousness over the cited claims is therefore clearly required.

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was made to include PVA, dextran, or any ionic polyol in the composition suggested by Dumutriu, Scopelianos, and Chen because Gombotz teaches that these were well known additives in this art at the time of the invention.

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

Applicant's comments regarding the withdrawn art rejection of record have been considered, but they do not address the above rejection.

Claims 14-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dumutriu, Scopelianos, and Chen as applied to claims 1, 3, 4, 6-8, 12-13, and 44 above, and further in view of Schlameus et al. (1994, U.S. Patent 5,294,446; reference

E). The claims are interpreted as above. In some dependent claims, the composition contains cells of various types.

The teachings of Dumutriu, Scopelianos, and Chen are relied upon as above. None of Dumutriu, Scopelianos, and Chen teaches a composition comprising cells.

Schlameus teaches a method for encapsulating osteoprogenitor cells in a biodegradable material (column 4, lines 26-40; column 6, line 21, through column 8, line 33). Schlameus teaches that the encapsulating material may be any biodegradable component, including chitosan and cellulose polymers, and that the material may contain more than one such component (column 2, line 67, through column 3, line 15). Schlameus teaches that the encapsulated cell composition may further comprise virtually any additional active agent, including growth factors, cytokines, extracellular matrix, and drugs (column 5, lines 34-60).

A person of ordinary skill in the art would have had a reasonable expectation of success in encapsulating live cells using a hydrogel made by combining chitosan, a polysaccharide such as HEC, and glyoxal as suggested by Dumutriu, Scopelianos, and Chen because Schlameus teaches that chitosan and cellulose derivatives are suitable for encapsulating cells. The selection of the hydrogel components in used to encapsulate the cells of Schlameus would therefore have been a routine matter of optimization on the part of the artisan of ordinary skill. A holding of obviousness over the cited claims is therefore clearly required.

Furthermore, the person of ordinary skill in the art would have had a reasonable expectation of including additional active agents such as those recited in claim 14 in the

Art Unit: 1651

composition suggested by Dumutriu, Scopelianos, and Chen because Schlameus teaches that almost any active agent can be incorporated into similar hydrogels. Furthermore, Dumutriu and Scopelianos explicitly indicate that active agents may be included in the hydrogels.

The selection of the type of cell to encapsulate in the hydrogel suggested by Dumutriu, Scopelianos, and Chen using the method of Schlameus would have been a routine matter of optimization on the part of the artisan of ordinary skill, said artisan recognizing that the explicitly stated utility of Schlameus is the regeneration of tissue. Therefore, selecting a cell type corresponding to the tissue to be regenerated or repaired would have constituted routine optimization at the time of the invention. A holding of obviousness over the cited claims is therefore clearly required.

For these reasons, it would therefore have been obvious to a person of ordinary skill in the art at the time the invention was made to use the hydrogel suggested by Dumutriu, Scopelianos, and Chen to encapsulate cells as suggested by Schlameus.

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

Applicant's comments regarding the withdrawn art rejection of record have been considered, but they do not address the above rejection.

Claims 1-19, 30, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al. (2002, *Journal of Pharmaceutical Sciences* 91: 1669-1677; reference C5 on 11/1/07 IDS) taken in view of Scopelianos (1989, U.S. Patent

Art Unit: 1651

4,877,775), Schlameus et al. (1994, U.S. Patent 5,294,446), and Gombotz et al. (1999, U.S. Patent 5,900,238). The claims are interpreted as discussed above.

Li teaches a hydrogel made by combining an acidic solution of chitosan with a solution of beta-glycerolphosphate, and hydroxyethylcellulose (HEC) in an ice bath (page 1670, under "Hydrogel Preparation"). Li teaches such a hydrogel further comprising pilocarpine, a bioactive substance (page 1670, under "In Vitro release of pilocarpine").

Li does not teach including glyoxal in the composition. Li does not teach encapsulating cells with the composition. Li does not teach including PVA or dextran in the composition.

Scopelianos teaches that glyoxal, when added to solutions of chitosan, promotes gelling of the chitosan (Examples 3a-3c at column 5).

Schlameus teaches a method for encapsulating osteoprogenitor cells in a biodegradable material (column 4, lines 26-40; column 6, line 21, through column 8, line 33). Schlameus teaches that the encapsulating material may be any biodegradable component, including chitosan and cellulose polymers, and that the material may contain more than one such component (column 2, line 67, through column 3, line 15). Schlameus teaches that the encapsulated cell composition may further comprise virtually any additional active agent, including growth factors, cytokines, extracellular matrix, and drugs (column 5, lines 34-60).

Gombotz teaches that compositions useful for encapsulating bioactive substances may include components that promote adhesion of the composition to tissues, e.g. polyvinyl alcohol and dextrans (column 6, line 55, through column 7, line 4).

A person of ordinary skill in the art would have had a reasonable expectation of success in adding the glyoxal solution of Scopelianos to the chitosan solution of Li because Scopelianos teaches that glyoxal causes chitosan to form a gel. The skilled artisan would have been motivated to include glyoxal in the composition of Li in order to make a gel immediately.

The selection of the component in which to include HEC (i.e., the chitosan solution or the glyoxal solution) would have been a routine matter of optimization on the part of the artisan of ordinary skill, since the cited prior art suggests that when chitosan, HEC, and glyoxal are combined, a hydrogel suitable for immobilizing bioactive substances is yielded; the order in which the components are added is not inventive in the absence of evidence to the contrary. In *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946), the court found that selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results. In *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930), the court found that selection of any order of mixing ingredients is *prima facie* obvious. See M.P.E.P. § 2144.

The selection of the amount of each component to include in the composition would have been a routine matter of optimization on the part of the artisan of ordinary skill. A holding of obviousness over the cited claims is therefore clearly required.

A person of ordinary skill in the art would have had a reasonable expectation of success in including physiological diluents such as phosphate buffer, salt solutions, and other nutrients in the composition of Li because Li teaches that the composition is compatible with additional components (see page 1670). The skilled artisan would have been motivated to include such diluents because Li teaches that the composition is intended for administration to subjects (see, e.g., the Abstract).

A person of ordinary skill in the art would have had a reasonable expectation of success in encapsulating live cells using the hydrogel of Li because Schlameus teaches that chitosan and cellulose derivatives are suitable for encapsulating cells. The selection of the hydrogel components in used to encapsulate the cells of Schlameus would therefore have been a routine matter of optimization on the part of the artisan of ordinary skill. A holding of obviousness over the cited claims is therefore clearly required.

Furthermore, the person of ordinary skill in the art would have had a reasonable expectation of including additional active agents such as those recited in claim 14 in the hydrogel of Li because Schlameus teaches that almost any active agent can be incorporated into similar hydrogels.

The selection of bioadhesive components to include in the hydrogel of Li would have been a routine matter of optimization on the part of the artisan of ordinary skill, said artisan recognizing that Gombotz teaches that hydroxyl-containing polymers and ionic polyols are useful in such compositions. A holding of obviousness over the cited claims is therefore clearly required.

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was made to add glyoxal to the composition of Li because Scopelianos teaches that it promotes fast gelling and to use the hydrogel of Li to encapsulate cells because Schlameus teaches that such hydrogels may be used in such applications. It would have been further obvious to a person of ordinary skill in the art at the time the invention was made to include various additional bioactive factors in the composition because Gombotz suggests that the biocompatibility of hydrogels is affected by the addition of such factors.

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

Applicant's comments regarding the withdrawn art rejection of record have been considered, but they do not address the above rejection.

No claims are allowed. No claims are free of the art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

Art Unit: 1651

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is (571)272-1928. The examiner can normally be reached on Monday-Thursday, 9:00am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lora E Barnhart/
Primary Examiner, Art Unit 1651